PATENT COOPERATION TREATY

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| From the INTERNATIONAL SEARCHING AUTHORITY | PCT | | | |
|---|---|--|--|--|
| To: McDERMOTT, WILL & EMERY Attn. Gadiano, Willem F. 600 13th Street, N.W. Washington DC 20005-3096 UNITED STATES OF AMERICA | NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION (PCT Rule 44.1) | | | |
| | Date of mailing (day/month/year) 07/08/2002 | | | |
| Applicant's or agent's file reference | FOR FURTHER ACTION See paragraphs 1 and 4 below | | | |
| 58049-018 International application No. PCT/US 01/44817 | International filing date (day/month/year) 30/11/2001 | | | |
| Applicant | | | | |
| WEISSMAN, GLENN H. | | | | |
| The applicant is hereby notified that the International Search Filing of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claim When? The time limit for filing such amendments is normal International Search Report; however, for more defined. | ns of the International Application (see Rule 46): | | | |
| Where? Directly to the International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Fascimile No.: (41-22) 740.14.3 | | | | |
| For more detailed instructions, see the notes on the according | | | | |
| 2. The applicant is hereby notified that no International Search Article 17(2)(a) to that effect is transmitted herewith. | th Report will be established and that the declaration under | | | |
| 3. With regard to the protest against payment of (an) addition the protest together with the decision thereon has been applicant's request to forward the texts of both the protest. | onal fee(s) under Rule 40.2, the applicant is notified that: en transmitted to the International Bureau together with the otest and the decision thereon to the designated Offices. | | | |
| no decision has been made yet on the protest; the ap | pplicant will be notified as soon as a decision is made. | | | |
| 4. Further action(s): The applicant is reminded of the following: Shortly after 18 months from the priority date, the international of the applicant wishes to avoid or postpone publication, a notion priority claim, must reach the International Bureau as provide completion of the technical preparations for international publications. | application will be published by the International Bureau. be of withdrawal of the international application, or of the d in Rules 90 <i>bis</i> .1 and 90 <i>bis</i> .3, respectively, before the cation. | | | |
| Within 19 months from the priority date, a demand for internation wishes to postpone the entry into the national phase until 30 m | onal preliminary examination must be filed if the applicant nonths from the priority date (in some Offices even later). | | | |
| Within 20 m nths from the priority date, the applicant must per before all designated Offices which hav not been lected in priority date or could not be elected because they are not bou | form the prescribed acts for ntry into the national phase the demand or in a later election within 19 months from the | | | |
| Name and mailing address of the International Searching Authority | Authorized officer | | | |

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NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international pbulication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been its filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will n t be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- [Where originally there were 48 claims and after amendment of some claims there are 51]:
 "Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers;
 claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- [Where originally there were 15 claims and after amendment of all claims there are 11]: "Claims 1 to 15 replaced by amended claims 1 to 11."
- 3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]: "Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or "Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- 4. [Where various kinds of amendments are made]: "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international appplication is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

_ T.A.

PATENT COOPERATION TREATY

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| | *** | SOD FUDTUED | see Notification of | Transmittal of | Internat | ional Search Report |
|---|--|---|--|------------------------------------|----------------------|--|
| Applicant's or agent's | tile reference | FOR FURTHER ACTION | (Form PCT/ISA/22 | 20) as well as, | where a | pplicable, item 5 below. |
| 58049-018 | - No | International filing date (da | nv/month/year) | (Earliest) Pr | iority Da | te (day/month/year) |
| International application | on NO. | | | , , | | |
| PCT/US 01/448 | 317 | 30/11/20 | 01 | | 01/3 | 2/2000 |
| Applicant | | | | | | |
| | | | | | | |
| WEISSMAN, GLE | INN H. | | | | | |
| This International Se according to Article | earch Report has bee 18. A copy is being tr | n prepared by this Internatio ansmitted to the Internationa | nal Searching Auth Il Bureau. | ority and is tra | nsmitted | to the applicant |
| This International Se | earch Report consists | of a total of4 | sheets. | | | |
| X It is | also accompanied by | a copy of each prior art doc | ument cited in this | report. | | |
| | | | | | | |
| 1. Basis of the re | to the lenguage the | international search was ca | rried out on the bas | is of the interr | ational a | application in the |
| language in | which it was filed, un | less offerwise indicated the | | | | |
| Aut | nority (Bule 23.1(b)). | vas carried out on the basis | | | | |
| b. With regard | to any nucleotide at | nd/or amino acid sequence | disclosed in the in | ternational ap | olication, | the international search |
| l was carried | out on the basis of the | ne sequence listing . onal application in written for | | | | |
| | | ernational application in com | | n. | | |
| 1 | | o this Authority in written for | | | | |
| | ished subsequently t | o this Authority in computer (| readble form. | | | |
| the inte | statement that the su | bsequently furnished written as filed has been furnished. | sequence listing d | | | |
| the | statement that the int | formation recorded in compu | iter readable form is | s identical to th | ne writter | n sequence listing has been |
| | | | . IV | | | |
| | | und unsearchable (See Bo) | Cij. | | | |
| 3. Un | ity of invention is la | cking (see box ii). | | | | |
| 4. With regard to | the title. | | | | | |
| | | submitted by the applicant. | | | | |
| | | ished by this Authority to rea | d as follows: | | | • |
| | | | | | | |
| 5. With regard to | the abstract | | | | | |
| | to the approved on a | submitted by the applicant. | | | | |
| <u></u> | | ished, according to Rule 38. ne date of mailing of this inte | 2(b), by this Author mational search re | ity as it appea port, submit co | rs in Box omments | III. The applicant may, to this Authority. |
| | | blished with the abstract is F | | 54 | | <u></u> |
| 1 | suggested by the app | | | | X | None of the figur s. |
| | | alled to suggest a figure. | | | | |
| | | er characterizes the invention | n. | | | |

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 01/44817

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61K31/715 A61P11/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC $\,7\,$ $\,$ A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, EMBASE, CHEM ABS Data

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No | | |
|------------|--|----------------------|--|--|
| Х | US 4 207 312 A (FUJII MITSUHARU ET AL) 10 June 1980 (1980-06-10) column 6, line 49-53; claim 1 | 1,2 | | |
| X | DATABASE WPI Section Ch, Week 200062 Derwent Publications Ltd., London, GB; Class B04, AN 2000-645782 XP002206314 & RU 2 148 991 C (KRASFARMA STOCK CO), 20 May 2000 (2000-05-20) abstract | 1,2 | | |
| x | EP 0 392 888 A (ANDERMANN GUY) 17 October 1990 (1990-10-17) page 3, line 9-21; claim 1; example 1 page 3, line 55,56 | 18 | | |

| Further documents are listed in the continuation of box C. | Patent family members are listed in annex. |
|---|---|
| Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed | *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *&* document member of the same patent family |
| Date of the actual completion of the international search | Date of mailing of the international search report |
| 18 July 2002 | 07/08/2002 |
| Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016 | Authorized officer Tardi, C |

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INTERNATIONAL SEARCH REPORT

International Application No PCT/US 01/44817

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Į F | Relevant to claim No. |
|------------|--|-----|-----------------------|
| Calegory | pliation of document, with indicatory, was approximately | | |
| A | "The Merck Index" 1996 , MERCK RESEARCH LABORATORIES , WHITEHOUSE STATION, NJ XP002206678 page 1227, paragraph 7276 -page 1228 | | |
| Y | WO 00 25588 A (MED GEN INC ;INNOVATIVE CHEMICAL CORP (US)) 11 May 2000 (2000-05-11) page 6, line 19 -page 7, line 6; claims 1-9; table 1 | | 1-22 |
| Y | EP 0 137 302 A (ANASCO GMBH) 17 April 1985 (1985-04-17) page 4, line 10-25 | | 1-22 |
| Y | US 4 556 557 A (REICHERT DIETRICH) 3 December 1985 (1985-12-03) column 3, line 61 -column 4, line 11; claims 3,6,10,11; examples 1-3 column 5, line 67 -column 6, line 9 | | 1-22 |
| Y | GB 2 333 450 A (MARSHTECH INTERNATIONAL LTD) 28 July 1999 (1999-07-28) claim 15 | | 1-22 |
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International application No. PCT/US 01/44817

INTERNATIONAL SEARCH REPORT

| Box I | Observati ns where certain claims were found unsearchable (Continuation of Item 1 of first sh et) |
|-----------|---|
| This Inte | ernational Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons: |
| 1. X | Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely: Although claims 17-20 and 22 are directed to a method of treatment of the human body, the search has been carried out and based on the alleged |
| 2. | effects of the composition. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically: |
| з | Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a). |
| Box II | Observations where unity of invention is lacking (Continuation of item 2 of first sheet) |
| | ternational Searching Authority found multiple inventions in this international application, as follows: |
| 1. | As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims. |
| 2. | As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee. |
| 3. | As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.: |
| 4. | No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: |
| R ma | Th additional search fe s were accompanied by the applicant's protest. No protest accompanied the paym int of additional search fees. |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 01/44817

| Patent docu cited in search | | Publication date | | Patent family member(s) | | Publication date |
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